

## **REMARKS**

In the Office Action, the Examiner rejected claims 1-7 and 9-25. By this paper, Applicants renumbered claims 9-25 due to a typographical error that originally skipped claim 8. As a result, the application now includes original claims 1-24 and new claims 25-33. Applicants also amended current claims 1-4 and 7-24 for clarification of certain features to expedite allowance of the present application. These amendments do not add any new matter. Upon entry of these amendments, claims 1-33 will be pending in the present application and are believed to be in condition for allowance. In view of the foregoing amendments and the following remarks, Applicants respectfully request reconsideration and allowance of all pending claims.

Applicants also stress that the present and previous amendments are not believed to narrow the scope of the claims as these amendments have been made to clarify the claimed subject matter and to more precisely conform the claimed subject matter to the disclosure. However, if these amendments narrow elements of the claims in any way, then Applicants emphasize that these embodiments are not made for reasons relating to patentability. These amendments merely clarify the elements of the claims and are neither necessary nor required to overcome rejections under 35 U.S.C. §§ 101, 102, 103, 112, or other relevant laws relating to patentability. For these reasons, Applicants do not surrender any potentially existing or future equivalents relating to elements of the present claims.

### **Claim Objections**

The Examiner objected to Claim 8 as being missing from the claims. Applicants have renumbered the claims such that previous claims 9-25 are now numbered as claims 8-24. Accordingly, Applicants respectfully request withdrawal of the objection.

### **Rejections under 35. U.S.C. § 112**

The Examiner rejected claims 12-18 under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps. Specifically, the Examiner stated:

Claims 12-18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omissions amounting to a gap between the steps. See MPEP §2172.01. The omitted steps are: the step of actually infusing the fluid

into a patient is omitted from the claim as well as providing the actual fluid warming and infusion system of claim 1.

Office Action, page 2. As amended, present claim 11 (former claim 12) recites, *inter alia*, a step of “passing the warmed fluid into the patient via a patient insertion device coupled to the tube.” Further, current claim 11 does not recite the use of an “infusion system of claim 1.” For these reasons, Applicants respectfully request withdrawal of the rejection of claim 11 under 35 U.S.C. § 112 as well as the rejection of all claims depending therefrom.

### **Rejections under 35. U.S.C. § 102**

The Examiner rejected claims 1 and 12 (now claim 11) under 35 U.S.C. § 102 as being anticipated by Maruschak (US 5,601,894) and as being anticipated by Swenson (US 5,195,976). Specifically, the Examiner stated:

The Maruschak reference discloses the device and use of a fluid warming and infusion system for infusing a warm fluid into a patient comprising a device that transfers heat to the fluid, see col. 1 lines 38-61 & col. 6 line 61-col. 7 line 47, thereby warming the fluid and an insulated tube seen in figures 1A-C that transports the warmed fluid to the patient wherein the insulated tube includes a substantially thermally insulating component that prevents the warmed fluid from losing a substantial amount of heat as the fluid flows through the tube.

The Swenson reference discloses the device and use of a fluid warming and infusion system for infusing a warm fluid into a patient comprising a device 41 that transfers heat to the fluid, thereby warming the fluid and an insulated tube 32 that transports the warmed fluid to the patient wherein the insulated tube includes a substantially thermally insulating component 47 that prevents the warmed fluid from losing a substantial amount of heat as the fluid flows through the tube, also see figure 3 and col. 6 lines 24-48.

Office Action, page 3.

Applicants respectfully traverse these rejections. Anticipation under Section 102 can be found only if a single reference shows exactly what is claimed. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 U.S.P.Q. 773 (Fed. Cir. 1985). For a prior art reference to anticipate under Section 102, every element of the claimed invention must be identically shown in a single reference. *In re Bond*, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). To maintain a proper

rejection under Section 102, a single reference must teach each and every element or step of the rejected claim. *Atlas Powder v. E.I. du Pont*, 750 F.2d 1569 (Fed. Cir. 1984). Thus, if the claims recite even one element not found in the cited reference, the reference does not anticipate the claimed invention.

The present application discloses a fluid delivery system and method to infuse a warmed fluid into the circulatory system of a patient. The system insulates the fluid as it travels through tubing *before* reaching the patient. Insulation of the fluid is provided by an insulating medium contained within the tube. By integrating insulation into the tube itself, the claimed system and method allow the tube to provide insulating properties without the addition of external components to the tube. Turning to the claims, the present independent claim 1 recites, *inter alia*, “a tube having insulation integrated into the tube configured to be disposed external to the patient and to transport the warmed fluid to the patient to prevent the warmed fluid from losing a substantial amount of heat as the fluid flows through the tube, wherein the tube is configured to attach to a patient insertion device disposed in the patient.” Further, present independent claim 11 recites, *inter alia*, “passing the warmed fluid through a tube having insulation integral to the tube and being disposed external to the patient, the tube being configured to transport the warmed fluid to the patient to prevent the warmed fluid from losing a substantial amount of heat as the fluid flows through the tube.”

***The Maruschak reference is missing features recited by independent claims 1 and 11***

The Maruschak reference does not teach or suggest “insulation integrated into the tube” as recited by present claim 1 or “insulation integral to the tube” as recited by present claim 11. In sharp contrast, the Maruschak reference teaches an external “insulation covering” that maybe wrapped about a patient’s IV administration tubing 9. Maruschak col. 4 line 6-9; Figs. 1A-4D. As disclosed, the insulating covering is a separate component that must be wrapped about the exterior of the tubing that forms the patients IV administration tubing 9. Thus, the Maruschak reference does not disclose tubing having integral insulation as recited by independent claims 1 and 11. In view of these deficiencies among others, the Maruschak reference cannot anticipate independent claim 1 and 11 and their dependent claims.

***The Swenson reference is missing features recited by independent claims 1 and 11***

The Swenson reference does not teach or suggest “a tube having insulation...to prevent the warmed fluid from losing a substantial amount of heat as the fluid flows through the tube” as recited by present claim 1. Nor does the Swenson reference teach “passing the warmed fluid through a tube having insulation integral to the tube...to prevent the warmed fluid from losing a substantial amount of heat as the fluid flows through the tube” as recited by present claim 11. The Swenson reference discloses a heat exchange system that includes “heater elements located between the IV tube 32 and an electrically and/or thermally insulating outer skin 47.” Swenson col. 6 lines 46-48. Accordingly, the system in Swenson is not limited to insulating the fluid in an intravenous tube from losing heat, but is instead the tubing 32 is configured to *promote* the transfer of heat across the tube’s boundaries. For example, as seen in Fig. 3 of Swenson, the disclosed system includes a heater wire 48 wrapped about the tube 32 that allows heat to be conducted through the tube 32 and into the fluid. The insulating outer skin 47 does not prevent heat from being conducted through the tube, as recited by the present claims, but instead directs heat from the heater elements to conduct through the tube 32 and into the fluid. Thus, the Swenson reference does not disclose insulated tubing that is configured to prevent heat loss. In view of these deficiencies among others, the Swenson reference cannot anticipate independent claim 1 and 11 and their dependent claims. For these reasons, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 102 of claims 1 and 11, as well as the rejection of all claims depending therefrom.

**Rejections under 35 U.S.C. § 103**

The Examiner rejected claims 1-2, 4, 7, 9-13, 15, 18-20, 22 and 25 under 35 U.S.C. § 103(a) as being unpatentable over Ford et al (US 5,381,510) and further in view of Verkaart (US 5,063,994). Specifically, the Examiner stated:

The Ford reference discloses the use of a fluid warming and infusion system for infusing a warm fluid into a patient in figure 1 comprising a heat exchanger cassette that transfers heat to the fluid, thereby warming the fluid and a fluid line. Now even though the Ford reference does not explicitly disclose an insulated tube attention is directed to Verkaart. The Verkaart reference teaches the use of an insulated tube/patient line in figures 3-6 that transports the warmed fluid to the patient wherein the insulated tube

includes a substantially thermally insulating component, seen as the heat exchanger fluid, that prevents the warmed fluid from losing a substantial amount of heat as the fluid flows through the tube, see col. 2 line 56 – col. 3 line 46.. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to utilize the teaching of Verkaart with the device of Ford in order to provide a warmed fluid to the patient without substantial heat loss over the course of infusion and to allow a fluid of a desired temperature to be delivered even over a low flow rate to the patient.

With respect to claims 2, 7, 13, 18, 20, & 25, wherein the insulated tube has a configuration consisting of an outer wall, an inner wall that forms a fluid lumen for transporting the warmed fluid, and at least two partitions connected between the inner and outer walls for forming at least two insulating gaps between the inner and outer walls and wherein the partitions are spaced about 180 degrees apart from each other, see Verkaart figure 4.

With respect to claims 4, 15, & 22, wherein each insulating gap is filled with an insulating material, wherein the heat exchange fluid is seen to be an insulating material.

With respect to claim 11, further comprising a luer connector 32 attached to a distal end of said insulated tube, see Verkaart figure 3 and col. 3 lines 13-28.

Office Action, pages 4-5.

Applicants respectfully traverse this rejection. The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (PTO Bd. App. 1979). Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching or suggestion supporting the combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). Accordingly, to establish a *prima facie* case, the Examiner must not only show that the combination includes *all* of the claimed elements, but also a convincing line of reason as to why one of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 U.S.P.Q. 972 (B.P.A.I. 1985). When prior art references require a selected combination to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gained from the invention itself, i.e., something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination. *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988).

As discussed previously, the present application discloses and claims an integral insulated tube that includes an insulating medium to prevent heat loss from a fluid as it travels through a tube *before* reaching a device disposed in a patient. Turning to the claims, the present independent claim 1 recites, *inter alia*, “a tube having insulation integrated into the tube configured to be disposed external to the patient and to transport the warmed fluid to the patient to prevent the warmed fluid from losing a substantial amount of heat as the fluid flows through the tube, wherein the tube is configured to attach to a patient insertion device disposed in the patient.” Further, present independent claim 11 recites, *inter alia*, “passing the warmed fluid through a tube having insulation integral to the tube and being disposed external to the patient, the tube being configured to transport the warmed fluid to the patient to prevent the warmed fluid from losing a substantial amount of heat as the fluid flows through the tube.” Also, present independent claim 18 recites *inter alia*, a patient tube that “comprises a tube having an integral insulating component and being disposed external to the patient, the tube being configured to prevent a warmed fluid from losing a substantial amount of heat as the warmed fluid flows through the tube, wherein the second end is configured to attach to a patient insertion device disposed in the patient.”

The cited references, taken alone or in hypothetical combination, fail to teach or suggest the claimed subject matter. In contrast, the primary reference, Verkaart, discloses a heat exchanger including a warming fluid to transfer heat from the warming fluid to a “physiological fluid, or infusate, to be heated.” Verkaart col. 2 lines 36-47. Of first concern, in this configuration the Verkaart reference does not provide for insulating the fluid, but instead provides for a heat exchange to warm the fluid. “Insulate” is defined as “to cover, line or separate with a material that prevents or reduces the passage, transfer, or leakage of heat, electricity, or sound.” *Random House Webster’s College Dictionary*, Random House, Inc. 1992. In accordance with the defined meaning of “insulate,” the Verkaart reference does not insulate the fluid to be delivered to the patient, but, in contrast, it promotes the exchange of heat between the warming fluid and the fluid to be warmed.

Moreover, the Ford reference fails to obviate the deficiencies of the Verkaart reference. The Ford reference merely discloses a heat exchanger cassette to transfer heat to a fluid, and it does not disclose an insulated tube as set forth in the present claims. In view of these deficiencies among others, the cited references taken alone or in hypothetical combination, cannot render obvious the current independent claims 1, 11 and 18 and their dependent claims. For these reasons, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 103(a) of claims 1, 11, and 18, as well as the rejection of any claims depending therefrom.

In addition to the above rejection, the Examiner rejected claims 3, 5-6, 14, 16-17, 21 and 23-24 under 35 U.S.C. § 103(a) as being unpatentable over Ford et al (US 5,381,510) and further in view of Verkaart (US 5,063,994) as applied to claim 1 and further in view of Dobak, III (US 6,042,559). Specifically, the Examiner stated:

Now even though Ford in view of Verkaart does not explicitly disclose the use of a vacuum on insulating foam in the insulated tube attention is directed to Dobak, III. The Dobak, III reference teaches the use of an insulated tube with a vacuum wherein the insulating material is comprised primarily of air or an insulated tube wherein the insulating material comprises insulating foam, see figure 4 and col. 4 lines 62-65, col. 5 line 52-col. 6 line 29. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to utilize the teachings of Dobak III with the device of Ford in order to provide a tube that is compacted and well insulated.

Office Action page 5.

Applicants respectfully traverse this rejection. As discussed previously, the Ford reference and the Verkaart reference taken alone or in hypothetical combination, fail to teach or suggest features recited by present independent claims 1, 11 and 18 from which the claims rejected by the Examiner depend. In addition, the Dobak reference fails to obviate the deficiencies of Ford and Verkaart.

First, the Dobak reference does not teach or suggest “a tube having insulation integrated into the tube...external to the patient...wherein the tube is configured to attach to a patient insertion device disposed in the patient” as recited by independent claim 1. Nor does it recite

“passing the warmed fluid through a tube...being disposed external to the patient, the tube being configured to transport the warmed fluid to the patient...passing the warmed fluid into the patient via a patient insertion device coupled to the tube” as recited by claim 11. In addition, it does not recite “a patient line comprising...a tube...being disposed external to the patient...configured to attach to a patient insertion device disposed in the patient” as recited by independent claim 18. In contrast, the Dobak reference discloses an insulated distal end 24 of a delivery catheter 16 that is used to insulate the patient from the chilled fluids as they pass *through the body* to perform hypothermia of a select organ or cells. Dobak col. 5 lines 52-53. In other words, the system disclosed by Dobak serves the function of allowing a chilled fluid to be introduced to a specific organ/region of the body while preventing the temperature of the chilled fluid from inadvertently causing damage to portions of the body as the fluids flow through delivery catheter 16 internal to the patient’s body. Accordingly, the Dobak reference discloses a tube wherein the portion that is disposed *within* the patient is insulated while hypothermia is performed on a patient, and it does not disclose an insulated tube external to the patient that is configured to attach to a patient insertion device disposed in the patient.

The Examiner has failed to point out any suggestion that exists to combine these references and, considering the differing of the operation and purpose of the cited references, there is no motivation to combine the references. For example, the cited references teach contrastingly different intended purposes and principles of operation. The Verkaart and Ford references disclose providing a warmed fluid to a patient via a heat exchanger. To provide a warmed fluid to the patient, heat exchangers surround a portion of tube in a location upstream from and external to the patient. In operation, the heat exchanger passes a fluid across the exterior of the tube to conduct heat into the fluid such that the fluid is warmed to a desired temperature and subsequently passes into the patient at a relatively comfortable temperature. In other words, the principle of operation of the primary references require that a fluid be warmed to about the patient’s body temperature before it is infused into the patient. In contrast, the Dobak reference discloses insulating the organs of a patient from chilled fluid as the chilled fluid is passed through the body in route to provide hypothermia of a select organ or location. To prevent the chilled fluid from damaging other organs or cells of patient, the Dobak reference provides a tube



with an insulated portion internal to the patient. Thus, the principle of operation of the secondary reference requires insulating only a portion of a delivery catheter that is disposed inside of the patient during hypothermia treatment of an organ.

Considering the two principals of operation, it is clear that a person of ordinary skill in the art would have no motivation to combine the references. For example, if the internal insulated tubing of Dobak was combined with the warmed fluid of the Verkaart and Ford references, no purpose would be served, as the fluid is at or near body temperature and, therefore, no need exists to insulate the fluid from the internal cells and organs of the patient. In the opposite, if the heat exchange properties of Verkaart and Ford were added to the chilled fluid transfer referred to in the Dobak reference, no purpose would be served as there is no adverse consequence of chilled fluid external to the patient, and, therefore, no desire for external insulation. Accordingly, there is no motivation to combine the Verkaart, Ford and Dobak references. For these reasons, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 103(a) of claims 1, 11, and 18, as well as the rejection of any claims depending therefrom.

### **Conclusion**

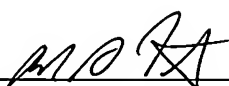
In view of the remarks set forth above, Applicants respectfully requests reconsideration of the Examiner's rejections and allowance of all pending claims. If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

### **General Authorization for Extensions of Time**

Furthermore, Applicants authorizes the Commissioner to charge the appropriate fee for the total of 9 added claims (consisting of one independent claim and eight dependent claims) and any additional fees which may be required, to the credit card listed on the attached PTO-2038. However, if the PTO-2038 is missing, if the amount listed thereon is insufficient, or if the amount is unable to be charged to the credit card for any other reason, the Commissioner is authorized to charge Deposit Account No. 06-1315; Order No. TYHC:0170/FLE (P0394CCS:P).

Respectfully submitted,

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Michael G. Fletcher  
Reg. No. 32,777  
FLETCHER YODER  
P.O. Box 692289  
Houston, TX 77269-2289  
(281-970-4545)